# Telephone Outreach to Increase Colorectal Cancer Screening in an Urban Minority Population

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The estimated 5-year survival rate from colorectal cancer (CRC) is greater than 90% for localized disease (stage 1), 1,2 yet in 2005, CRC is expected to cause 56290 deaths in the United States<sup>1</sup> and result in more than \$6.5 billion in health care costs.<sup>3</sup> Regular screening by the fecal occult blood test with follow-up treatment has been shown to reduce populationwide mortality by as much as 15% to 33%.4-7 Screening can also reduce CRC incidence by the removal of precursor lesions.<sup>8,9</sup> On the basis of these data from randomized trials, CRC screening for individuals older than 50 years has been advocated by governmental, 10 professional, 11 and private organizations12 and has been shown to be costeffective. 13-16 Nonetheless, the prevalence of CRC screening remains low, 17-20 particularly in low-income and minority populations, 21-24 who experience the highest rates of CRC mortality. 17,25-33

Black men and women have the highest incidence and mortality from CRC. During the period from 1992 to 2001, the annual CRC incidence was 13.2% greater for Black than for White men (72.9 vs 64.4 per 100 000) and 21.7% greater for Black than for White women (56.1 vs 46.1 per 100 000). During this period, the annual CRC mortality was 34% greater for Black than for White men (35.0 vs 26.1 per 100 000) and 38% greater for Black than for White women (24.9 vs 18.0 per 100 000).

Several factors may contribute to these higher mortality rates within the Black population, including disparities in participation in CRC screening and consequent later stages at diagnosis <sup>34–39</sup> and lower rates of receipt of standard therapies and follow-up care. <sup>38,40–43</sup> Of the 35 randomized trials of interventions to increase CRC screening published between 1978 and 2004 that we identified, <sup>44–78</sup> only 6 included a substantial number of Black participants. <sup>45,46,50,51,70,72</sup>

*Objectives.* We compared the effectiveness of a telephone outreach approach versus a direct mail approach in improving rates of colorectal cancer (CRC) screening in a predominantly Black population.

Methods. A randomized trial was conducted between 2000 and 2003 that followed 456 participants in the New York metropolitan area who had not had recent CRC screening. The intervention group received tailored telephone outreach, and the control group received mailed printed materials. The primary outcome was medically documented CRC screening 6 months or less after randomization.

Results. CRC screening was documented in 61 of 226 (27.0%) intervention participants and in 14 of 230 (6.1%) controls (prevalence rate difference = 20.9%; 95% CI = 14.34, 27.46). Compared with the control group, the intervention group was 4.4 times more likely to receive CRC screening within 6 months of randomization.

Conclusions. Tailored telephone outreach can increase CRC screening in an urban minority population. (*Am J Public Health.* 2006;96:2246–2253. doi:10. 2105/AJPH.2005.067223)

Only 3 studies evaluated a tailored telephone intervention, <sup>63,64,77</sup> and none of these included large numbers of Black participants. The effectiveness of telephone outreach on several cancer screening behaviors has been demonstrated, <sup>79,80</sup> but no randomized trial to evaluate telephone outreach as a method to increase CRC screening in a predominantly Black population has been conducted. We therefore conducted a randomized trial to evaluate tailored telephone outreach compared with mailed printed material to increase CRC screening in a predominantly Black population of low to moderate income.

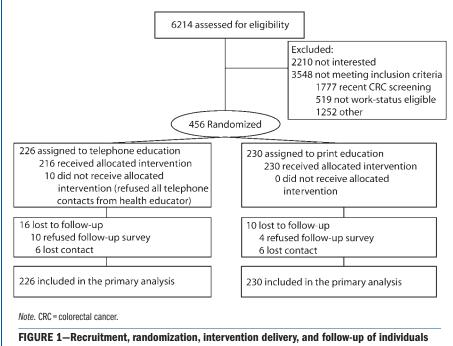
# **METHODS**

# **Study Design**

A 2-group randomized trial with blinded ascertainment of outcomes was conducted. Eligibility was assessed by telephone, a baseline interview was completed, and individuals were invited to participate. Consenting participants were randomized in a 1:1 ratio to receive a tailored telephone educational intervention or mailed printed materials about CRC screening. Six months after randomization, medical claims and records were reviewed.

# **Setting and Participants**

The study was conducted in the New York City metropolitan area. The sampling frame was constructed from membership lists of a health benefit fund comprising approximately 250 000 members (or beneficiaries). Through the benefit fund, all these individuals had health insurance coverage that included coverage for CRC screening. Inclusion criteria were: age older than 52 years, no self-report of a recent CRC screening (defined as a home stool test within the past 2 years, a flexible sigmoidoscopy within the past 5 years, or a colonoscopy or barium enema within the past 10 years), no scheduled appointment for a CRC screening test, accessibility by telephone, ability to identify a current primary care physician, and consent to participate. Exclusion criteria included self-report of prior diagnosis of colorectal polyps, inflammatory bowel disease, colorectal cancer, or other cancer that had been treated within the past 5 years; stated intention to travel or to move away from the region within the subsequent 6



participating in an evaluation of telephone outreach to increase colorectal cancer screening.

months; being unemployed, retired, or unable to work because of disability; enrollment of someone else in the household into the study; or another medical condition that precluded meaningful participation in the study.

### **Enrollment and Randomization**

Individuals were blocked according to gender and age (52 to 54, 55 to 59, 60 to 64, 65 to 69, 70 to 74, and 75 to 79 years) and assigned randomly within blocks to 1 of the 2 treatment groups. Between November 1, 2000, and June 30, 2002, a total of 6214 individuals were contacted by telephone to assess eligibility and interest in the study. Of these, 2210 (35.6%) were not interested, 3548 (57.1%) were interested but not eligible, and 456 (7.3%) were interested, eligible, and randomized. Randomization was conducted with a table of random permutations.<sup>81</sup> The enrollment cascade is shown in Figure 1. There were no significant differences between the intervention (n=226) and control (n=230) groups with respect to demographic characteristics (Table 1). The sample was more than 70% female, almost two thirds were Black, approximately 62% were married or living together, and almost half

were aged between 55 and 59 years. More than half had a high-school degree or less, whereas approximately 35% had some college or technical school. Although more than 94% of the sample were employed full time, 71% reported an annual household income of less than \$50,000.

# **Interventions**

The control group received printed materials sent by first-class mail within a week of randomization, and none of these mailed materials were returned. These materials consisted of a cover letter welcoming participants into the study and a brochure published by the Centers for Disease Control and Prevention.<sup>82</sup> The brochure included information about CRC, how it can be prevented through early detection and treatment, the asymptomatic nature of the disease, descriptions of the various kinds of recommended screening tests, and a message to the reader to talk with his or her physician and to seek screening.

The intervention group received tailored telephone education based on several behavioral sciences and educational theories.83 The intervention began within 2 weeks of randomization with the intent of attaining the

following goals: establishing a positive and trusting rapport with the recipient; reinforcing accurate knowledge and healthful beliefs, correcting misconceptions, and bolstering motivation to obtain a CRC screening on the basis of the participant's readiness and individual cognitive factors; addressing identified barriers (e.g., fear, transportation) and skill deficits that could impede CRC screening; providing social and emotional support for obtaining CRC screening; and eliciting a verbal commitment to obtain CRC screening. Emphasis was placed on positive reinforcement, enhancement of perceived self-efficacy to overcome barriers, and the message that there is support from scientists, medical doctors, and health organizations for recommended screening. The intervention was semistructured, and the frequency and duration of contact varied considerably among participants. The median number of intervention calls was 5, and the median number of total telephone minutes spent per participant was 23.5. The telephone intervention was implemented (1 or more calls completed) in 216 of 226 (95.6%) of those assigned to intervention. Ten intervention group participants declined participation after randomization.

# **Outcome Criteria and Sample Size Determination**

The primary outcome was receipt of CRC screening within 6 months of randomization. The outcome criteria were met by receipt of a 3-day fecal occult blood test (defined as 2 samples from each of 3 consecutive bowel movements), sigmoidoscopy, colonoscopy, or a barium enema. A single stool test (defined as a single sample of stool obtained and tested for occult blood during a medical examination) was not considered an acceptable CRC screening outcome. 10,84

Because of exclusion of those who had received CRC screening in the period before randomization, the sample size determination was based on the assumption that baseline prevalence rates of CRC screening would be zero in both groups. We projected that in the control group, 25% of men and 20% of women would receive CRC screening within 6 months of randomization and that in the telephone outreach group 40% of men and 30% of women would receive screening within 6

TABLE 1—Demographic Characteristics of Participants in a Randomized Trial of Telephone Outreach Versus Mailed Information to Increase Colorectal Cancer Screening: New York City Metropolitan Area, 2000–2003

	Intervention (n = 226), % (No.)	Control (n = 230), % (No.)	Total Sample (N = 456), % (No.)
Gender			
Men	30.1 (68)	27.8 (64)	28.9 (132)
Women	69.9 (158)	72.2 (166)	71.1 (324)
Age, y			
52-54	19.5 (44)	25.7 (59)	22.6 (103)
55-59	47.8 (108)	43.5 (100)	45.6 (208)
≥60	32.7 (74)	30.9 (71)	31.8 (145)
Race			
Black	67.7 (153)	58.7 (135)	63.2 (288)
White	13.7 (31)	18.7 (43)	16.2 (74)
Other	17.7 (40)	21.7 (50)	19.7 (90)
Refused	0.9 (2)	0.9 (2)	0.9 (4)
Marital status			
Single/never married	6.6 (15)	6.5 (15)	6.6 (30)
Married/living together	63.3 (143)	60.4 (139)	61.8 (282)
Divorced/separated	21.2 (48)	25.7 (59)	23.5 (107)
Widowed	8.0 (18)	7.0 (16)	7.5 (34)
Refused	0.9 (2)	0.4 (1)	0.7 (3)
Education			
Less than high school	11.9 (27)	7.8 (18)	9.9 (45)
High school graduate	46.0 (104)	40.4 (93)	43.2 (197)
Some college/technical school	31.9 (72)	38.7 (89)	35.3 (161)
College or beyond	10.2 (23)	12.6 (29)	11.4 (52)
Refused	0	0.4 (1)	0.2 (1)
Work status			
Part time	6.6 (15)	5.2 (12)	5.9 (27)
Full time	93.4 (211)	94.8 (218)	94.1 (429)
Annual household income, \$			
< 30 000	22.6 (51)	23.9 (55)	23.2 (106)
30 000-50 000	50.4 (114)	45.2 (104)	47.8 (218)
>50000	24.3 (55)	26.1 (60)	25.2 (115)
Do not know/refused	2.7 (6)	4.8 (11)	3.7 (17)

months of randomization. The necessary sample sizes per group for a power of 0.80 were found to be 207 for men and 395 for women on the basis of these effect sizes, for a 1-tailed test with  $\alpha{=}.01.^{81}$  In December 2001, on the basis of an unplanned interim analysis, self-reported CRC screening outcomes in each group were reported to the funding agency. At that time 306 participants had been randomized. The interim analysis showed that the screening rate among controls was much lower than anticipated and that the absolute and proportional difference between groups

was greater than expected. These data, which were not shared with the staff, and budgetary reductions made by the funding agency led to a decision to stop recruitment in June 2002 and to analyze the data using a 2-sided  $\alpha$  level of .05, without further adjustment for the interim analysis. At that time the total number of randomized participants was 456.

# **Data Collection and Measures**

In a baseline prerandomization telephone interview, trained interviewers used a structured interview format to collect demographic data. Race/ethnicity was based on self-classification. Determination of prerandomization CRC screening was based on the telephone interview. Six months after randomization, we interviewed all participants by telephone and read a description of a single office stool test, a home stool test, flexible sigmoidoscopy, and colonoscopy. Participants were asked whether or not they had had each test within the past year. Participants who responded affirmatively were asked the date of the test, where the test was conducted, and the health care provider's name, address, and telephone number. Subjects who did not complete a 6-month followup survey (26 or 5.7% of the 456 randomized participants; 16 intervention and 10 control participants) were assumed not to have had a CRC screening test. A total of 85 intervention and 21 control participants reported having either a home stool test, flexible sigmoidoscopy, or colonoscopy within 6 months of being randomized. Research staff, unaware of the participants' intervention status, contacted the provider by telephone to verify each self-report of a CRC screening test. Physicians, who were not told which CRC screening test the participant had reported, were asked to complete, sign, and return a faxed form to verify whether or not their patient had had a CRC screening test within the specified dates. Physicians were asked to document the specific test, the date of examination, and whether or not there were positive findings. Repeated contacts were made (either by telephone or in person) as necessary. For participants who reported CRC screening and for whom verification through a medical record was not obtained, we relied on the health benefit fund's billing claims files. These billing claims files were audited on a regular basis for all CRC-related procedures incurred throughout the study period. The health benefit billing claims files were used only to verify a colonoscopy or flexible sigmoidoscopy when medical record data were not obtained. Billing claims files were not used to verify a home stool test because the claims data could not distinguish between a single or home stool test. Data from physicians and billing claims files were coded by research staff and confirmed by the project director. Among the 75 verified CRC screening tests, 64 tests were confirmed on the basis of medical records and

TABLE 2—Participants Screened for Colorectal Cancer and Relative Risk, by Intervention/Control Group and Demographic Characteristics: New York City Metropolitan Area, 2000–2003.

Group	Intervention, %	Control, %	Relative Risk (95% CI)
Total sample (N = 456)	27.0	6.1	4.4 (2.6, 7.7)
Gender			
Women (n = 324)	25.9	6.6	3.9 (2.1, 7.3)
Men (n = 132)	29.4	4.7	6.3 (2.0, 20.1)
Age, y			
52-54 (n = 103)	20.5	6.8	3.0 (1.0, 9.2)
55-59 (n = 208)	29.6	8.0	3.7 (1.8, 7.7)
$\geq$ 60 (n = 145)	27.0	2.8	9.6 (2.3, 39.6)
Race <sup>a</sup>			
Black (n = 288)	28.8	6.7	4.3 (2.2, 8.5)
White (n = 74)	22.6	4.6	4.9 (1.1, 21.8)
Other (n = 90)	25.0	6.0	4.2 (1.2, 14.1)
Education <sup>a</sup>			
High school or less (n = 242)	25.2	7.2	3.5 (1.7, 7.3)
More than high school (n = 213)	29.5	4.2	7.0 (2.8, 17.3)
Marital status <sup>a</sup>			
Married (n = 282)	24.5	6.5	3.8 (1.9, 7,6)
Not married (n = 171)	32.1	4.4	7.2 (2.6, 19.8)
Income, \$a			
$\leq$ 50 000 (n = 324)	24.2	5.0	4.8 (2.3, 10.0)
> 50 000 (n = 115)	36.4	5.0	7.3 (2.3, 23.1)

<sup>&</sup>lt;sup>a</sup>Numbers do not add up to total sample because of nonresponse.

11 tests were confirmed through the health benefit fund's billing claims files.

# **Statistical Analysis**

Rates of CRC screening between the 2 groups were calculated. Estimates of the relative risks and 95% confidence intervals were computed with the FREQ procedure of SAS (version 9.1.2; SAS Institute Inc, Cary, NC); these were used to assess differences between the groups for the total sample and subgroups. All analyses were based on intention to treat.

# **RESULTS**

Table 2 presents the percentage screened for CRC in the intervention and control groups, the relative risk of screening for intervention versus control, and a 95% confidence interval for the relative risk 6 months after randomization. The first line shows that in the total sample of 456, 27% (n=61) of the intervention group and 6.1% (n=14) of the control group received screening for CRC.

Thus, screening rates were 4.4 times higher (95% confidence interval [CI]=2.6, 7.7) for the intervention group than the control group; the absolute difference between the screening rates was 20.9% (95% CI=14.34, 27.46). The screened percentages and relative risks are also shown separately for gender, age, race, education level, marital status, and income. There was an intervention effect within each of the subgroups.

Of the 61 individuals in the intervention group who had a verified test, 29 had a 3 day fecal occult blood test, 29 had a colonoscopy, 2 had a flexible sigmoidoscopy, and 1 had a 3-day fecal occult blood test followed by a colonoscopy. Among the 14 controls who received CRC screening, 13 had a colonoscopy and 1 had a 3-day fecal occult blood test followed by a sigmoidoscopy. Seven of 226 intervention participants and 13 of 230 controls reported having only a rectal examination and single stool test in the physician's office.

On the basis of claims data, we identified 21 individuals (18 intervention participants

and 3 controls) who received medically significant diagnoses or subsequent medical treatment or both as a result of CRC screening. In the intervention group, of the 29 who had a colonoscopy and 2 who had a flexible sigmoidoscopy, 1 was found to have malignant cancer of the rectosigmoid junction and 1 was found to have malignant colon cancer. Eleven were found to have a benign neoplasm of the colon, 2 were found to have a benign neoplasm of the colon, rectum, or anal cavity as well as internal hemorrhoids, 2 were found to have internal hemorrhoids, and 1 was found to have a benign neoplasm of the rectum or anal cavity. Among the 13 controls who had a colonoscopy and 1 who had a flexible sigmoidoscopy, 2 had a benign neoplasm of the colon removed and 1 was found to have noninfectious gastroenteritis and colitis.

### **DISCUSSION**

To our knowledge, this is the first study to demonstrate that telephone outreach can increase the rate of CRC screening in an urban minority population. The magnitude of the intervention effect was dramatic, compared with the mailed information, as measured by relative risk estimates or differences between groups in the proportion of the population screened. The intervention effect was consistent for all the demographic subgroups examined

We found that some patients received a single fecal occult blood test in the physician's office. Randomized trial data<sup>4–9</sup> and consensus recommendations <sup>10–12</sup> for CRC screening supporting the use of fecal occult blood testing to screen for CRC were based on 3-day samples collected at home. Individuals in the intervention group were more likely to receive 1 of the recommended CRC screening procedures and were also less likely to receive a single test in the physician's office (7 of 226 vs 13 of 230), consistent with the interpretation that patient education and motivation through telephone outreach can influence physicians' decisionmaking.

Despite the increase in recommended screening in the intervention group, a large percentage did not receive screening within the 6-month window, even after tailored telephone outreach. In our population, we

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enrolled only individuals who had not recently received recommended CRC screening. Thus, enrolled individuals were less likely to receive this preventive care than the larger population in our sampling frame. All study participants were employed and had health insurance (with zero copayments for CRC screening), so the barriers to CRC screening in our sample were independent of direct medical costs to participants. An earlier analysis of barriers to CRC screening<sup>85–88</sup> in this population revealed several impediments to asymptomatic individuals seeking CRC screening, including difficulty accessing the 3-day fecal occult blood test despite having health insurance, other health issues that took precedence over CRC screening, lack of familiarity with CRC screening guidelines and tests, and lack of support from significant others. Collectively, these barriers reflect the challenges in increasing rates of CRC screening behavior in this population. A considerable proportion (35.6%, n=2210) of the target population who were approached (n= 6214) chose not to participate. This group may be even more difficult to reach.

The great majority of colon cancers arise from adenomatous polyps that have progressed from smaller to larger nonmalignant polyps, followed by dysplasia and malignancy. Progression generally occurs over 10 years or more.<sup>89</sup> The recognition that adenomatous polyps are precursors for colorectal cancer, together with the long time period over which progression generally occurs, provides the biological rationale for screening. The optimal strategy for CRC screening remains a subject of ongoing investigation. Currently recommended modalities include direct or radiographic visualization, in which the goal is to identify and remove locally confined cancers and polyps. Alternatively, because many locally confined cancers and polyps bleed, fecal testing for occult blood, followed by colonic visualization if positive, has been found in clinical trials to be an effective screening strategy. 4-7 Screening strategies generally target those older than 50 years because approximately 90% of cases of CRC occur after this age. 90 Despite publication more than 12 years ago of clinical trial data showing that CRC screening reduces cause-specific mortality,4 national data from the Centers for Disease

Control and Prevention Behavioral Risk Factor Surveillance System indicate that the reported rates of CRC screening remain low. In 2001, for those aged 50 and older, these rates were 23.5% reporting receipt of fecal occult blood testing within the previous year and 38.7% reporting lower endoscopy within the previous 5 years. CRC screening rates are lower among Black Medicare beneficiaries than among Whites. 92

Of the 35 CRC intervention studies we identified published between 1978 and 2004, none evaluated tailored telephone outreach in a predominantly Black population. Many of these studies promoted a specific screening test, such as the fecal occult blood test 44–46,49–52,56–73,76 or sigmoidoscopy, 48,53,78 some promoted both the fecal occult blood test and sigmoidoscopy, 47,54,55,70,74,75,77 and 2 promoted other preventive health behaviors in addition to CRC screening. 46,54

Of the 32 studies promoting the fecal occult blood test, only 1 did not distribute the fecal occult blood test kit or recruit participants with office visits already scheduled; however, the study relied on a self-reported outcome. <sup>46</sup> Our study did not specify a specific procedure or distribute kits but rather encouraged the participants to select a screening test after discussion with their physician, as suggested by some researchers. <sup>93–96</sup>

Three studies to date represent the best developed efforts to evaluate tailored telephone communications as part of an overall strategy to promote CRC screening. 63,64,77 These studies involved distribution of fecal occult blood test kits through mail<sup>63,64,77</sup> or in-person pickup at worksites.<sup>77</sup> In the first study by Myers et al., 63 participants (n=837) were randomly assigned to 1 of 4 conditions. Those who received only a reminder letter reported low rates of screening (27%), participants who received telephone calls to address questions and prompt them to complete the test reported significantly higher rates of testing (37%), and participants who had 2 reminder calls plus a discussion of barriers to nonadherence and counseling to overcome those barriers reported even higher rates of testing (48%). In the second study by Myers et al.,64 participants (n=646) were randomly assigned to 1 of 2 conditions. Those who received a reminder letter, an education

booklet, and a tailored educational phone call had higher rates of testing (50%) than those who received only a reminder letter (29%).

In the third study, by Tilley et al.,<sup>77</sup> participants (n=5042) were randomly assigned by worksite to 1 of 2 conditions. Those who received a standard worksite program plus a tailored education booklet and 2 tailored phone calls had a higher rate of compliance (23%) than control participants receiving a standard program (19%).

These studies demonstrated that educational telephone calls are effective at increasing adherence to CRC screening. However, these studies were conducted among primarily White participants, included printed materials along with telephone outreach so that independent effects of each could not be determined and did not encourage interaction with physicians because fecal occult blood test kits were distributed.

There were several strengths of our study. Our outcome ascertainment method included verification of screening by the use of medical records or, in some instances of a colonoscopy, billing claims, rather than selfreport. These data were ascertained by staff blinded to the participant's intervention status. Limitations of the study include following participants for only 6 months after randomization and intervening only with patients and not providers. The study population all had health insurance and a physician, and this is both a strength and a limitation. This characteristic of the study sample allowed us to focus on characteristics of the patient and health care system rather than insurance and medical costs to patients. Tailored telephone outreach may not be equally effective among patients without health insurance or access or among patients with large copayments.

The participation rate reflects both the method of recruitment (by telephone) and the reluctance of the target population to address CRC screening. It is likely that those who agreed to participate were more predisposed, or less indisposed, to CRC screening than those who did not participate. Nonetheless, there were low rates of CRC screening in the sampled population, and none of the randomized participants had received recent CRC screening.

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In summary, to our knowledge, this is the first randomized trial demonstrating that a tailored telephone outreach intervention increases CRC screening in a predominantly minority sample. This increase was achieved without direct distribution of fecal occult blood test kits. The intervention was intended to create patient demand for appropriate CRC screening through interaction with physicians, rather than to promote a specific method of screening. Disparities in CRC mortality in Black populations, which can partly be explained by disparities in early detection and treatment, may be addressed in part by provider organizations or health plans making use of telephone outreach to patients to promote CRC screening. Further research is needed to identify low-cost methods for increasing CRC screening uptake, especially in Black populations at increased risk for CRC mortality.

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# Contributors

C.E. Basch originated the study, supervised all aspects of its implementation, interpreted the study findings, and led the writing of the article. R.L. Wolf provided day-to-day leadership and management of the study and direct supervision of study personnel and assisted with interpretation of findings, data analysis, and writing. C.H. Brouse assisted with the development and implementation of the intervention, data collection, and writing. C. Shmukler and A. Neugut assisted with the development and implementation of study protocols and provided medical oversight. L.T DeCarlo conducted data analyses and assisted with the interpretation of findings. S. Shea assisted with study design, development of study protocols, interpretation of study findings, and writing.

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## **Human Participation Protection**

The study was approved by the institutional review boards of Teachers College, Columbia University, and the Columbia University Medical Center. Informed consent was obtained from all participants.

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